

## REMARKS

Claims 1-12 and 31-42 are currently pending, and have been rejected in the outstanding office action. Reconsideration is requested.

Claims 1-12 and 31-42 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Gambale (U.S. Pub. No. 20030208209). Applicant respectfully traverses the rejection for the reasons discussed below.

Examiner acknowledges that Gambale does not disclose a septum being removable from between the first and second openings, as recited in claim 1, or first and second ports, as recited in claim 31, and that Gambale does not disclose the septum being adapted for abrading adjacent tissue. However, the Examiner states that "[i]t would have been obvious to one of ordinary skill in the art at the time of invention to provide a removable septum that provides the methods of abrading adjacent tissue as disclosed by Gambale, in order to selectively abrade the tissue (using mechanical means **884** in Figure 41, for instance) resulting in the initiation of a healing process on the tissue surfaces and also to facilitate separation of the tissue from the tissue positioning device."

The rationale for modifying the Gambale device as proposed by the Office Action is not supported by the reference itself. The Office Action does not cite to any disclosure in the Gambale reference that suggests there is any issue separating the tissue from the capsule, so it is unclear how the prior art suggested this modification. Nor is there any teaching in Gambale for how the mid-wall of the capsule body **852** might be removed. Specifically, there is nothing that suggests, much less teaches, how the wall of the capsule body **852** could be displaced to achieve the benefits proposed by the Office Action. In particular, the Office Action fails to explain *where* the wall of the capsule body **852** could be displaced *to* without a major reconstruction of the entire device, since there is no apparent cavity for accommodating the capsule body **852**.

Because the wall of the cavity body **852** is disposed between the first and second folds of tissue in the longitudinal direction, it is also not obvious from the teachings of Gambale how one could initiate removal of this structure, particularly after the suture step as proposed by the Office Action. Moreover, it must be remembered that Gambale extolled the virtues of a "single piece injection molded unit" as an advance over the prior art. [¶0017] The removable wall proposed by the Office Action would appear to necessitate a multi-piece unit, and in the process eviscerate the expressed advantage of the Gambale disclosure. An objective reading of the Gambale reference alone cannot fairly teach or suggest the major reconstructions proposed by the Office Action, and in fact the proposed modifications are expressly contradicted by Gambale's advocating of a "single piece injection molded unit."

Furthermore, the Office Action states that: "The septum may be removable after the suctioning and suturing steps so that the folds of tissue may still be maintained in order to apply further abrasion to the tissue." [O.A., p. 4]. However, after the suturing step the channel **894** of the Gambale device will be occupied by the suture **878**. This condition would presumably preclude any lateral movement of the wall portion of the body capsule **852** in between the two compartments (otherwise the suture would be stretched and possibly jeopardized). Longitudinal movement of the wall structure at issue would apply normal pressure to one surface and relieve pressure on a second surface, neither of which would achieve any of the benefits that the Office Action asserts would be achieved by making the structure removable. The curved shape of the sides of the wall structure at issue (see Figure 40 cited by Office Action) suggest that a radial movement of the wall, even assuming such a movement could be accomplished, would not abrade the tissue once it had been sutured. Rather, the curved wall would simply fall away from the tissue or apply normal pressure to the tissue, depending upon the direction of the radial movement. Thus, the Office Action has failed to demonstrate how any of the benefits claimed in its proposed modification of Gambale could be physically

achieved, and has similarly failed to demonstrate how Gambale could be modified to achieve a removable septum that would produce the alleged benefits.

In a telephone interview with the Examiner on August 1, 2007, the Examiner agreed with counsel for Applicant that there is no motivation or suggestion in Gambale to remove the transverse wall portion of body capsule **852** for the following reasons previously stated in Applicant's response filed August 6, 2007. In two previous Office Actions, the Examiner has sought to overcome the acknowledged shortcomings of Gambale with the teachings of first McAlister and then Redmond. When both of these proposed combinations were demonstrated by the Applicant to be improper, the Examiner concluded that Gambale alone rendered the claimed invention obvious, but has failed to show how one of ordinary skill in the art, armed only with the Gambale reference, would have found it obvious to reconfigure the Gambale device, where such reconfiguration removed an expressed benefit of the Gambale device (single piece injection molding).

In view of the foregoing, Applicant respectfully submits that claims 1-12 and 31-42 are patentable over Gambale and that all pending claims are now in condition for allowance. Reexamination and reconsideration of the application are respectfully requested and allowance at an early date is solicited.

The Commissioner is authorized to charge deposit account no. 06-2425 for any unforeseen fees arising from the filing of this paper.

Respectfully submitted,

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